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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,918	03/16/2004	Claude Singer	1662/495071	9628
23838	7590	01/11/2005		
KENYON & KENYON 1500 K STREET, N.W., SUITE 700 WASHINGTON, DC 20005			EXAMINER HABTE, KAHSAY	
			ART UNIT 1624	PAPER NUMBER

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application N .</b>	<b>Applicant(s)</b>	
	10/800,918	SINGER ET AL.	
	Examiner Kahsay Habte, Ph. D.	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 November 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 48-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 48, 50, 59-60, 64 and 73 is/are rejected.
- 7) Claim(s) 49,51-58,61-63 and 65-72 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                         |                                                                             |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.                                               |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|                                                                                                                         | 6) <input type="checkbox"/> Other: _____.                                   |

### **DETAILED ACTION**

1. Claims 48-73 are pending.

#### ***Response to Amendment***

2. Applicant's amendment filed 11/18/2004 in response to the previous Office Action (07/19/2004) is acknowledged. Rejection of claims 48 and 50 under 35 U.S.C. § 112, second paragraph (paragraph 4) has been maintained.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48, 50, 59-60, 64 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention: In claims 48 and 51, the phrases, "about 90% or greater" or "about 95% or greater" are not clear. The term "greater" is ambiguous when it follows "about 90%" or "about 95%". For example for the phrase "about 90% or greater", it is unclear if the term "greater" applies to the 90% (i.e. greater than 90%, e.g. 91%) or if it applies for the phrase "about 90%" (i.e. greater than about 90%, e.g. 88%, 89%, 90%, 91%, etc.). The latter covers both greater and lower percentage numbers of the 90%. The same is true for the phrase "about 95% or greater". If the greater applies to the "95%", percentage numbers such as 96%, 97% are covered. In other hand, if the term "greater" applies to "about 95%", percentage

numbers such as 94%, 95.2%, 96%, etc. are covered. See *Ex parte Lee*, 31 USPQ 2nd 1105, 1107; *Amgen vs. Chugai*, 13 USPQ 2nd 1737, 1787; 18 USPQ 2d 1016, 1030.

Suggested is "about 90% or greater than 90%" for claim 48 and 60 and "about 95% or greater than 95%" for claims 50, 59, 64 and 73. Note that claim language in claims 49, 51, 58, 63, 65 and 72 are acceptable.

### ***Response to arguments***

Applicant's argument filed 11/18/2004 has been fully considered but it is not persuasive.

Applicants argue: "Words of approximation, such as "about" are generally not definite and can be found in virtually every chemical patent....., in view of the specification, would know with sufficient definiteness what "about 90%" means. Indeed, the office action seems to suggest that "about 90%" would not have been considered indefinite but for the addition of the words "or greater." However. If "about 90%" is understood by one skilled in the art, then the amount greater than about 90% is no less definite or understandable. Likewise, "about 95% or greater" is also sufficiently definite." The examiner disagrees with applicants. Applicant's argument is based on the definition of the terms "about" and "about 90%" or "about 95%" that are not the same as the phrases "about 90% or greater" or "about 95% or greater". The definiteness of the word "about" does not make definite the phrases "about 90% or greater" and "about 95% or greater". Applicants are relying on the fact that "about" or "about 90%" is definite and reach a conclusion that the phrases "about 90% or greater" and "about

“95% or greater” are also definite. The phrases “about 90% or greater” and “about 95% or greater” remain indefinite, since it is unclear what is covered and what is not.

In *Ex parte Lee*, on page 1107, it has been disclosed: “Appellant’s claim recitation of ‘less than about 5 grams/10 minutes’ is indefinite, perhaps sufficiently so that a rejection under the second paragraph of 35 U.S.C. 112 would have been appropriate.” In *Amgen vs. Chugai*, 13 USPQ 2nd 1737, on page 1787, it has been disclosed that “at least about 160,000” is indefinite. In *Amgen vs. Chugai*, 18 USPQ 2nd 1016, on page 1030, the court held claim 4 and 6 of the U.S. Patent 4,677,195 patent invalid because of “at least about 160,000”. Note that “at least about” and “less than about” are not different from applicant’s claim language “about 90% or greater” or “about 95% or greater”.

### ***Objection***

4. Claims 49, 51-58, 61-63 and 65-72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Conclusion***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674, if there is no reply within 24 hours, James Wilson (Acting SPE) can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kahsay Habte, Ph. D.  
Examiner  
Art Unit 1624



Mark L. Berch  
Primary Examiner  
Art Unit 1624

KH  
January 5, 2005